

HIGH CLINICAL ACCEPTANCE OF METVIX[®] PDT

PhotoCure ASA

Second Quarter Report 2002

Highlights:

- **Marketing of Metvix[®] PDT in Europe Progressing as Planned**
- **Positive Phase III Clinical Results in the Treatment of Nodular BCC in the US**
- **Patient Enrolment Completed for First Phase III Clinical Trial with Hexvix[®] for Bladder Cancer – Interim data positive**
- **Patient Enrolment Ongoing in Pilot Study with Benzvix[®]**
- **PhotoCure Investment in Anticancer Therapeutic Inventions AS**
- **Strong Financial Position**

Marketing of Metvix[®] PDT Progressing as Planned

Following the issuance of the Finnish marketing authorisation in May, PhotoCure now holds national marketing authorisations for Metvix[®] PDT (Photodynamic Therapy) in all the Nordic countries. In Sweden, product specialists are currently marketing Metvix[®] PDT, while pre-launch activities, such as price and reimbursement applications and educational programmes in the use of Metvix[®] PDT, are ongoing in Norway, Denmark and Finland. In addition, successful market introduction conferences were held in May in Finland and Denmark. At present, a total of 126 lamps have been installed at 86 centres in the Nordic countries.

Metvix[®] PDT is, as of today, approved in 14 European countries and in New Zealand. Marketing authorisations have been issued in Sweden, Norway, Denmark, Iceland, Germany, United Kingdom, Ireland, Luxembourg, Finland, Greece, and New Zealand, while applications are pending in Switzerland, Australia and the US.

Galderma S.A. is stepping up its preparations to launch Metvix[®] PDT on the world's major pharmaceutical markets and more resources have been allocated for Metvix[®] PDT than for any other product in its portfolio. Metvix[®] PDT was a main focus at Galderma's exhibition stand at the World Congress of Dermatology in Paris, and five scientific presentations were held on the clinical studies of Metvix[®] PDT. In addition, Galderma sponsored a separate Metvix[®] PDT symposium. PhotoCure was also present at the UICC International Cancer Congress in Oslo, where the company hosted a successful symposium on the Clinical Benefits of Photodiagnosis and PDT in the Treatment of Cancer.

In April, PhotoCure filed papers in an Australian court to invalidate Australian patent number 624985 assigned to Queen's University in Kingston, Canada, and licensed to DUSA Pharmaceuticals Inc.. PhotoCure asserts that publications that predate the Queen's University patent preclude the patenting of 5-aminolevulinic acid for photodynamic therapy.

Positive Clinical Results in the Treatment of Nodular BCC Obtained in the US

PhotoCure has recently completed a complex clinical trial of Metvix[®] PDT in nodular BCC. Because nodular lesions are often deep, they are usually excised surgically, leaving the patients with scars. In the trial, the nodular lesions were first treated with photodynamic therapy and 6 months later removed surgically. The specimens were examined for remaining cancer cells and since the presence of a single cancer cell is interpreted as non-complete response, this study methodology gives a very strict, conservative assessment of treatment efficacy. FDA requires this type of evidence in order to approve new cancer treatments. Metvix[®] PDT proved far superior to the comparator, placebo PDT, with a complete clinical response rate of 82% (78% histologically verified). These results will be incorporated in the Metvix[®] NDA on BCC, which is scheduled to be submitted before the end of this year.

Patient Enrolment Completed for First Phase III Clinical Trial with Hexvix[®]

Phase III studies of Hexvix[®] are ongoing in Europe and in the US. Patient enrolment for the European Phase III study was completed during the second quarter of 2002. This study includes 286 patients in 22 leading university hospitals across Europe and is designed to document the safety and efficacy of Hexvix[®] fluorescence cystoscopy for the detection of bladder cancer. Another Phase III study has been initiated in Europe, and Phase III trials have been initiated at 17 leading urology centres in the US, following the US Food and Drug Administration's (FDA) approval of PhotoCure's Investigational New Drug (IND) application for Hexvix[®] in December 2001.

In the first Phase III study, there were no serious adverse events related to Hexvix[®]. Interim data confirm the positive results obtained in the Phase II study previously reported, and the first filing for marketing approval is expected during the first half of 2003. Market research has shown that there is a medical need for Hexvix[®] and PhotoCure is now preparing the launch of this promising product.

Patient Enrolment in Pilot Study with Benzvix[®]

Benzvix[®] is being developed as a product for photodiagnostics and photodynamic therapy for lesions in the gastro-intestinal tract, and the first patients are enrolled in a pilot study.

PhotoCure Subscribes Shares in Anticancer Therapeutic Inventions AS

PhotoCure has made an investment, amounting to NOK 5 million, in Anticancer Therapeutic Inventions AS (ATI) by subscribing shares amounting to 6.6% of the ATI shares. A shareholder's agreement gives PhotoCure an option to acquire, at a pre-set price per share, additional shares in ATI and thereby increasing its ownership to more than 60% of the outstanding shares in the company.

ATI is a Norwegian company that develops novel anticancer products based on α -particle radiation. Its lead product Alpharadin[™], a completely new concept within radiopharmaceuticals, is a bone metastases-seeking radiopharmaceutical, developed for selective irradiation of bone metastases. Approximately 80% of patients with advanced lung, prostate and breast cancer may develop bone metastases; hence there is a strong need for new therapies to delay tumour progression and relieve pain associated with these metastases. ATI is founded by researchers at the Norwegian Radium Hospital and the University of Oslo, and its competence in both radiopharmaceuticals and the treatment of bone metastases is internationally recognised.

PCI Biotech AS

PCI Biotech continues to focus its business on the opportunities for photochemical internalisation (PCI) in drug discovery, development and delivery of novel cancer therapeutics. PCI Biotech is

currently developing a proprietary photosensitiser, clinically optimised and specially designed for PCI. PCI Biotech's products for the research market, LumiSource[®] and LumiTrans[®] will be offered to potential licensing partners who have already established a strong position on this market.

Financial Position

Operating revenues totalled NOK 4.6 million for the second quarter of 2002, compared to NOK 2.6 million in the same period of 2001. Total operating expenses for the group amounted to NOK 34.0 million for the three months ending 30th of June 2002, compared to NOK 27.2 million during the same period of 2001. The increase is associated with product development activities as well as pre-marketing activities related to Metvix[®] PDT. Net loss for the group totalled NOK 27.2 million for the three months ending 30th of June 2002, compared to NOK 18.4 million in the same period in 2001. Net financial income has declined mainly due to a weakened Euro compared to NOK, which has resulted in an exchange loss.

Shareholders' equity totalled NOK 206.2 million as of 30th of June 2002 compared to NOK 259.4 as of 31st of December 2001. Due to the payment from Galderma in the beginning of the year, cash flow was neutral during the first 6 months. Total liquidity amounted to NOK 305.2 million as of 30th of June 2002 and is mainly invested in money market funds. The number of outstanding shares was 17,420,000 as of 30th of June 2002.

Profit & Loss (Group)

(all amounts in NOK 1,000 except per share data)

Three month ended			Six month ended		2001
30.06.02	30.06.01		30.06.02	30.06.01	1.1-31.12
4 594	529	Sales	8 291	931	2 330
6	2 061	Other operating revenues	130	2 686	3 022
4 601	2 590	Operating revenues	8 422	3 617	5 352
1 028	5 545	Salaries & other pers. costs	4 874	10 640	25 737
21 821	14 731	External R&D	45 356	27 551	78 036
312	182	Ordinary depreciation	545	341	758
10 884	6 712	Other operating costs	19 855	11 205	28 687
34 045	27 170	Total operating expenses	70 630	49 738	133 218
-29 444	-24 580	Operating loss	-62 208	-46 121	-127 866
5 411	6 771	Interests income	10 447	14 073	27 486
3 135	567	Interests expense	4 918	772	1 308
2 276	6 204	Net financial income	5 529	13 301	26 178
-27 169	-18 376	Loss before tax	-56 678	-32 820	-101 688
0	0	Taxes		0	0
-27 169	-18 376	Net loss	-56 678	-32 820	-101 688
-235	-96	Of this minority interests	-548	-102	-1 074
-1.56	-1.07	Net loss per share (1)	-3.26	-1.91	-5.93

(1) Calculation based on average weighted number of shares outstanding.

Balance sheet (all amounts in NOK 1,000)

	2002	2001	2001
	30.06	30.06	31.12
Fixed assets	11 413	2 479	3 935
Receivables	24 181	3 093	10 456
Securities	221 229	330 698	283 564
Cash & cash equivalents	83 930	31 901	21 614
Total assets	340 752	368 171	319 569
Shareholders' equity	206 212	325 836	259 398
Long term liabilities	17 524	17 152	17 362
Current liabilities	117 016	25 183	42 809
Total equity and liabilities	340 752	368 171	319 569